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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/821,667 | 04/09/2004 | Jagadish C. Sircar | AVANIR.124A | 8770 |

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| EXAMINER | |
|---|---|
| STOCKTON, LAURA LYNNE | |
| **ART UNIT** | **PAPER NUMBER** |
| 1626 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 09/05/2007 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/821,667 | SIRCAR ET AL. | |
| | Examiner | Art Unit | |
| | Laura L. Stockton, Ph.D. | 1626 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14,19-22 and 26-33* is/are pending in the application.

4a) Of the above claim(s) *5-14, 19-22 and 27-32* is/are withdrawn from consideration.

5)☒ Claim(s) *33* is/are allowed.

6)☒ Claim(s) *1-4 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

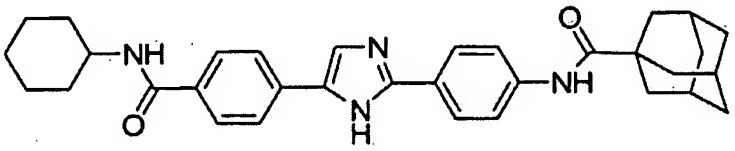
**DETAILED ACTION**

**Claims 1-14, 19-22 and 26-33 are pending in the application.**

***Election/Restrictions***

Applicant's election without traverse of Group I, and the species of Compound 127 on page 70, paragraph [0248], of the instant specification (reproduced below), in the reply filed on March 6, 2006 was acknowledged in a previous Office Action.

**N-Cyclohexyl-4-(2-(4-(1-adamantanamido)phenyl)-1H-imidazol-5-yl)benzamide (127)**




**127**

The requirement was deemed proper and therefore made FINAL in a previous Office Action.

Claims 5-25 and 27-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Election was made **without** traverse in the reply filed on March 6, 2006. Claims 15-18 and 23-25 were cancelled per the Amendment filed June 26, 2007.

In response to Applicant's inquiry concerning rejoinder, in accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. The products are not allowable for reasons stated below.

Rejections made in the previous Office Action that do not appear below have been overcome by Applicant's amendments to the claims. Therefore, arguments pertaining to these rejections will not be addressed.

## *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating allergic asthma, does not reasonably provide enablement for treating all allergic reactions associated with increased IgE levels. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

***The nature of the invention***

Applicant is claiming a product of formulas of Genus 1, Genus 2, Genus 3 or Genus 4 for treating an allergic reaction associated with increased IgE levels.

See, for example, instant claim 1. From the reading of the specification, it appears that Applicant is asserting that the embraced products, because of their mode action which involves lowering IgE levels, may be useful for treating all allergic reactions associated with increased IgE levels.

***The state of the prior art and the predictability or lack thereof in the art***

While the state of the art is high with regard to treating allergic asthma, the state of the art with regard to treating all allergic reactions associated with increased IgE levels is still being studied. For example, Howard et al. {CHEST, 123(3), March 2003, pages 363S-368S, Supplement} state "Allergic diseases are most likely due to interactions between genetic and environmental factors." Howard et al. further state "It is a major challenge to identify the genes responsible for susceptibility to complex multifactorial diseases such as asthma and BHR

(bronchial hyperresponsiveness). As these genes are delineated, determining the specific role of each gene in the development of asthma as well as characterizing gene-environment correlations are important areas of research. By understanding the basic genetic mechanisms that lead to the development of allergy and asthma, new therapeutic interventions will be developed that will be used to modify the development and clinical progression of these common disorders." Further, Applicant has not disclosed what other diseases/disorders are embraced by the language "allergic reactions associated with increased IgE levels". The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

***The amount of direction or guidance present and the presence or absence of working examples***

That a single class of compounds can be used to treat all allergic reactions associated with increased IgE levels which are embraced by the claims is an incredible finding for which Applicant has not provided supporting evidence. Applicant has not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for treating all conditions by the instant claimed products.

***The breadth of the claims***

The breadth of the claims is treating all diseases and disorders that are classified as allergic reactions associated with increased IgE levels.

***The quantity of experimentation needed***

The nature of the pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which products exhibit the desired pharmacological activities for each of the diseases and disorders embraced by the instant claims. The quantity of experimentation needed would be undue when faced with

the lack of direction and guidance present in the instant specification in regards to testing all diseases and disorders generically embraced in the claim language, and when faced with the unpredictability of the pharmaceutical art. Thus, factors such as "sufficient working examples", "the level of skill in the art" and predictability, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

***The level of the skill in the art***

Even though the level of skill in the pharmaceutical art is very high, based on the unpredictable nature of the invention and state of the prior art and lack of guidance and direction, one skilled in the art could not use the claimed invention without undue experimentation.

## *Response to Arguments*

Applicant's arguments filed June 26, 2007 have been fully considered but they are not persuasive. Applicant has amended the claims and states that the Examiner has indicated that treating an allergic reaction and/or asthma was enabled. In response, nowhere on the instant record does the Examiner indicate that the broad language of treating an allergic reaction associated with increased IgE levels is enabled. As now indicated above, the treatment of allergic asthma is enabled. Allergic asthma is the only specifically named disease/disorder disclosed in the instant specification. For all the reasons stated above, the rejection is deemed proper.

## *Allowable Subject Matter*

The elected species of Compound 127 is allowable over the art of record.

Claim 33 is allowed.

## *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory

action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 5-14, 19-22 and 27-32 drawn to an invention nonelected without traverse in the reply filed on March 6, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either

Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

August 27, 2007